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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/879,413	06/12/01	GILVARG	PRIN-0069

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HM12/1031

EXAMINER
LEARY, L

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 10/31/01

*Handwritten number 4*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/879,413

Applicant(s)

GILVARG, CHARLES

Examiner

Louise N. Leary

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on Preliminary Amendment 6-12-2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: CC

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1. Claims 1-3 are pending in this application.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugiyama et al (US Patent Number 4,551,272).

Sugiyama et al disclose an assay for measuring enzymatic activity of carboxypeptidase A in the sample in the presence or absence of a reaction inhibitor. Sugiyama et al disclose that carboxypeptidase A enzyme is found in the pancreas and the blood serum. Sugiyama et al also disclose a method wherein the activity of the carboxypeptidase A depends on the disease which is present and the extent of the disease. Note the abstract and columns 1-10.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugiyama et al (US Patent Number 4,432,896).

Sugiyama et al disclose an assay for measuring enzymatic activity of carboxypeptidase A in a sample in the presence or absence of a reaction inhibitor. Sugiyama et al disclose that carboxypeptidase A enzyme is a protein-decomposing enzyme found in the pancreas and the blood serum. Sugiyama et al also disclose a

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method wherein the activity of the carboxypeptidase A enzyme was measured. In addition, Sugiyama et al disclose that the activity of the enzyme carboxypeptidase A depends on the disease which is present and the extent of the disease. See the abstract and columns 1-4.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al (Analytical Biochem., Vol. 161, p219-225, (1987) in combination with Talley (US Patent 4,939,288(1990)).

The claims are directed to a method of enhancing sensitivity and specificity of an assay measuring enzymatic activity in a sample comprising measuring enzymatic activity in the sample in the presence or absence of a specific inhibitor of the enzymatic activity; a method of measuring carboxypeptidase A levels in a biological fluid by contacting the fluid with a carboxypeptidase A substrate in the presence and absence of an inhibitor of carboxypeptidase A and measuring changes in optical density; and a method of diagnosing acute pancreatitis in a patient by measuring carboxypeptidase A levels in a biological fluid by contacting the fluid with a carboxypeptidase A substrate in the presence and absence of an inhibitor of carboxypeptidase A and measuring changes in optical density.

Brown et al disclose an assay for determining carboxypeptidase A levels and activity in serum by contacting the serum with N-acetyl-phenylalanyl-3-thiaphenylalanine as a substrate. Brown et al also disclose an assay step which measures changes in absorbance after the substrate N-acetyl-phenylalanyl-3-thiaphenylalanine specific for carboxypeptidase A was contacted with a serum sample. In addition, Brown et al disclose that the sensitivity and precision of the assay increased when N-acetyl-phenylalanyl-3-thiaphenylalanine was used as substrate for carboxypeptidase A. Further, the assay was used to detect pancreatitis in patients. Note the abstract and pages 219-225. Thus, Brown et al disclose the method steps claimed except for stating that an inhibitor can be present.

However, with respect to using a specific inhibitor of the enzyme carboxypeptidase A, Talley disclose "...the activity of carboxypeptidase A has been found to be strongly inhibited by 2 (R)-benzyl succinic acid (Byres et al., "J. Biochem.", Vol. 247, p606 (1977))." Note page 3.

Hence, Brown et al disclose the method steps claimed except for stating that an inhibitor can be present in a method step for measuring enzymatic activity in a sample which was provided by Talley disclosing the inhibitor 2 (R)-benzylsuccinic acid is specific for the enzyme carboxypeptidase A.

It would have been obvious to one having ordinary skill in this art at the time this invention was made to provide the methods claimed for measuring enzyme activity in a sample wherein the enzyme can be carboxypeptidase A comprising the step of

measuring enzymatic activity in the presence and absence of a specific inhibitor because Brown et al disclose the method as claimed for measuring the activity and concentration of the enzyme carboxypeptidase A in a serum sample using N-acetyl-phenylalanyl-3-thiaphenylalanine as a substrate specific for carboxypeptidase A to detect pancreatitis except for describing the use of an inhibitor specific for an enzyme or specific for carboxypeptidase A provided by Talley disclosing 2 (R )-benzylsuccinic acid strongly inhibits carboxypeptidase A which is deemed to have previously provided sufficient guidance to practice the method of the claimed invention.

4. The Gilvarg reference (US 6,309,850) has been cited to further show the state of this art.

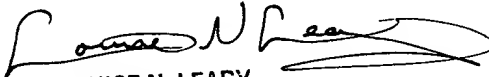
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 9:30 to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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LOUISE N. LEARY  
PRIMARY EXAMINER

October 30, 2001